

SECTION II REMARKS

Regarding the Amendments

Claims 20 and 27 have been amended as set forth in the above Complete Listing of the Claims. The amendments made are in accordance with suggestions provided by the examiner in the Office Action mailed April 10, 2007. As amended, the claims are supported by the specification and the original claims. No new matter has been added, as defined by 35 U.S.C. § 132.

Thus, upon entry of the amendments, claims 20-30 will be pending.

Claim Rejections Under 35 U.S.C. § 112 - Indefiniteness

The Examiner has rejected claims 20-30 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically claims 20 and 27 are alleged to be indefinite as lacking a step that provides a conclusion that matches the preamble of each claim. Applicants respectfully submit that claims 20 and 27, as amended, contain such a concluding statement.

The examiner's attention is respectfully drawn to amended claims 20 and 27, as set forth in Section I above. As amended, the claims contain the language:

"wherein the content of the transgene-coded protein or peptide in said transgenic [claim 27: potato] plant is increased relative to the content of the transgene-coded protein or peptide in a control plant of the same genetic background"

This language is as suggested by the examiner in the Office Action mailed April 10, 2007 and is in agreement with the preamble of each of claims 20 and 27, reciting "[a] method of increasing the content of one or more desired transgene-coded proteins or peptides in a transgenic [claim 27: potato] plant."

Accordingly, it is respectfully submitted that amended claims 20 and 27, and claims 21-26 and 28-30 dependent therefrom, meet the requirements of definiteness under 35 U.S.C. § 112, second paragraph. Removal of the rejection is therefore respectfully requested.

Claim Rejections Under 35 U.S.C. § 112 - Enablement

Additionally, the examiner has rejected claims 20-26 under 35 U.S.C. §112, first paragraph, as

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lacking enablement for a method of increasing the concentration of a transgene-coded protein in any species of plant other than a potato plant. Applicants respectfully disagree.

The examiner acknowledges that the prior art teaches that antisense constructs have been successful in suppressing the expression of endogenous ATP/ADP transporters in transgenic potatoes and tobacco, and that the present application teaches how to make an antisense construct comprising a cDNA from potato and how to transform a potato plant with this construct and provides the same as a working example. (Office Action mailed April 10, 2007, page 5.)

However, the examiner states that with regard to additional species, there is a high degree of unpredictability regarding which species of plants will produce an increase in protein or polypeptide in response to antisense inhibition of the plastidiary ATP/ADP transporter. The examiner refers to Reiser et al. in support of this assertion of unpredictability. (Office Action mailed April 10, 2007, page 5.)

The examiner's attention is respectfully drawn to the claims of the present application. Claim 20 recites a method of increasing the content of one or more <u>transgene-coded proteins</u> in a transgenic plant. It is pointed out that it is neither asserted in the application nor recited by the claims that the <u>total protein content</u> or the <u>content of an endogenous protein</u> of the plant is increased. It is the object of the present invention to change the ATP/ADP distribution in the plant in favor of the selective increase of the content of a <u>transgene-coded protein</u>, but <u>not to increase the total protein content</u>. This intent is expressed throughout the application, for example:

"The present invention comprises a novel mechanism of increasing the transgene-coded biomolecule content in organisms, such as plants..." (Specification, p. 3, 11. 2-3; emphasis added);

"The resulting transgenic plants were partially hypertransformed using another transgene. The plants obtained were subjected to a proteinchemical analysis, and the content of different foreign proteins and whole protein in tuber extracts was determined. It turned out that there was a marked increase in the <u>foreign protein content</u> in transgenic plants." (Specification, p. 4, 1. 29 to page 5, 1. 3; emphasis added);

"Within the meaning according to the present invention the transgene-coded biomolecules relate to both proteins and peptides as well as to nucleic acid molecules. In particular, peptides, proteins and nucleic acids which are not expressed naturally in the respective target organism are mentioned..."

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(Specification, p. 5, Il. 22-25; emphasis added.)

Reiser et al. report a reduced total protein content in the seeds of transgenic plants in which the endogenous plastidiary ATP/ADP transporter is either inhibited or knocked out, as well as a lower weight of the seeds and a retarded development of primary roots and leaves of transgenic plants. However, Reiser et al. do not describe the transgene-coded protein content of a desired transgene-coded protein, because the plants disclosed by Reiser et al. are not hypertransformed with a further transgene-coded protein. Therefore, any report in Reiser et al. of reduced protein content in seeds does not have any relation to reduced content of a specific transgene-coded protein. Reiser et al. only report that the content of endogenous storage protein was reduced in the seeds of ATP/ADP transporter knock-out plants. Thus, contrary to the assertion of the examiner, Reiser et al. is not inconsistent with the teaching of the present application, because they do not show a reduced content of transgene-coded protein and, therefore, do not indicate an unpredictability of inhibiting expression of a plastidiary ATP/ADP transporter in different species of plants to increase the specific content of a transgene-coded protein made in the plant. Hence, no unpredictability relating to the increase of a specific transgene-protein has been indicated in the art.

Tjaden et al., also cited by the examiner in the Office Action mailed April 10, 2007, describe transgenic potato plants comprising an antisense construct that suppresses the expression of plastidiary ATP/ADP transporters like that of the present invention. Like Reiser et al., Tjaden et al. report an altered morphology, e.g. smaller tuber size, and lower weight of tubers in transgenic antisense plants (see, e.g. Fig 4, p. 534 and Table 3, p. 535 of Tjaden et al.), due to the alteration of the metabolic path dependent on the plastidiary ATP/ADP transport. Hence, Tjaden et al. and Reiser et al. both report that the inhibition of the plastidiary ATP/ADP transporter impairs the growth and yield of the plant. However, this altered morphology does not show reduction of the content of a transgene-coded protein. In the present application the antisense constructs are applied in potato plants in addition to a marker gene and one or more further desired transgenes (se eindependent claims 20 and 27), showing that the antisense inhibition of the plastidiary ATP/ADP transporter increases the content of a desired transgene-coded protein in a hypertransformed transgenic plant. Hence, the present inv4ention shows that alteration of a metabolic path dependent on the plastidiary ATP/ADP transport (i.e. lipid synthesis in Arabidopsis (see Reiser et al.) or starch synthesis in potatoes (see Tjaden et al.)) by inhibiting the respective transporters does not impair the production of a further transgene-coded protein in the

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plant. In fact, an increase in transgene-coded protein in the plant is observed. Therefore, the teaching of Tjaden et al. relating to potatoes is consistent with the observations of Reiser et al. relating to *Arabidopsis* and the observations of the claimed invention. It is therefore predictable that the claimed method would be effective in *Arabidopsis*, as well as additional plant species, because the teaching of Reiser et al. is not contradictory to that of Tjaden et al., nor to that of the present specification.

Accordingly, the cited references show successful suppression of plastidiary ATP/ADP transporters in various plants and do not show reduction in transgene-coded protein production. The present application, therefore, building on the teachings of the prior art, provides sufficient guidance for a person skilled in the art to perform the claimed method in plants other than a potato plant without undue burden. Withdrawal of the rejection of claims 20-26 under 35 U.S.C. §112, first paragraph, as lacking enablement is therefore respectfully requested.

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CONCLUSION

Based on the foregoing, all of Applicants' pending claims 20-30 are patentably distinguished over the art, and are in form and condition for allowance. The Examiner is requested to favorably consider the foregoing and to responsively issue a Notice of Allowance.

The time for responding to the April 10, 2007 Office Action without extension was set at three months, or July 10, 2007. Applicants hereby request a one month extension of time under 37 C.F.R. § 1.136 to extend the deadline for response to and including August 10, 2007. Payment of the extension fee of \$60.00 specified in 37 C.F.R. § 1.17(a)(1), as applicable to small entity, is authorized by the enclosed Credit Card Payment Form PTO-2038. Should any additional fees be required or an overpayment of fees made, please debit or credit our Deposit Account No. 08-3284, as necessary.

If any issues require further resolution, the Examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss same.

Date: August 8, 2007

Date: August 8,3007

Respectfully submitted,

Steven J. Hultquist Reg. No. 28,021

Attorney for Applicants

Kelly K. Reynolds Reg. No. 51,154

Attorney for Applicants

INTELLECTUAL PROPERTY/ TECHNOLOGY LAW Phone: (919) 419-9350 Fax: (919) 419-9354 Attorney File No.: 4121-168

Enclosures:

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